UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,233	06/16/2005	Johannes Coy	4007.009	7127

30448 7590 06/29/2007

AKERMAN SENTERFITT
P.O. BOX 3188
WEST PALM BEACH, FL 33402-3188

EXAMINER	
REDDIG, PETER J	
ART UNIT	**PAPER NUMBER**
1642	

MAIL DATE	DELIVERY MODE
06/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,233	COY, JOHANNES	
	Examiner	Art Unit	
	Peter J. Reddig	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-43* is/are pending in the application.

4a) Of the above claim(s) *27-37 and 39-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The response filed on May 9, 2007 to the restriction requirement of March 9, 2007 has been received. Applicant has elected Group 20, claims 38, 40, 41, and 42 for examination. Because applicant did not distinctly and specifically point out any supposed errors in the restriction requirement, the election has been treated as an election without traverse MPEP 818.03(a).

In the response filed May 18, 2007, Applicants have amended claims 27-42 and added claim 43.

In view of the newly amended claims of May 18, 2007, the previous restriction requirement is hereby vacated and a new restriction requirement follows.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 27-35, drawn to a method for detection of carcinomas comprising a) obtaining a biological test sample from an individual b) determining the level DNase-X POLYPEPTIDE molecules in the test sample; c) comparing the level of DNase-X POLYPEPTIDE molecules within said sample to the contents within a corresponding control sample; d) finding an increased level of DNase-X POLYPEPTIDE in the test sample relative to the level of DNase-X in the control sample indicates the presence of a carcinoma or precursor lesion.

Group 2, claim(s) 27-35, drawn to a method for detection precursor lesions of carcinomas comprising a) obtaining a biological test sample from an individual b) determining the level DNase-X POLYPEPTIDE molecules in the test sample; c) comparing the level of DNase-X POLYPEPTIDE molecules within said sample to the contents within a corresponding control sample; d) finding an increased level of DNase-X POLYPEPTIDE in the test sample relative to

the level of DNase-X in the control sample indicates the presence of precursor lesions carcinoma or precursor.

Group 3, claim(s) 27-33, 36, and 37, drawn to a method for detection of carcinomas comprising a) obtaining a biological test sample from an individual b) determining the level DNase-X NUCLEIC ACID molecules in the test sample; c) comparing the level of DNase-X NUCLEIC ACID molecules within said sample to the contents within a corresponding control sample; d) finding an increased level of DNase-X NUCLEIC ACID in the test sample relative to the level of DNase-X in the control sample indicates the presence of a carcinoma.

Group 4, claim(s) 27-33, 36, and 37, drawn to a method for detection of precursor lesions or carcinomas comprising a) obtaining a biological test sample from an individual b) determining the level DNase-X NUCLEIC ACID molecules in the test sample; c) comparing the level of DNase-X NUCLEIC ACID molecules within said sample to the contents within a corresponding control sample; d) finding an increased level of DNase-X NUCLEIC ACID in the test sample relative to the level of DNase-X in the control sample indicates the presence of a precursor lesions of a carcinoma .

Group 5, claim(s) 39 drawn to a method of identifying and obtaining a drug candidate for treatment of carcinomas and their precursor lesions comprising the following steps: a) contacting a DNase-X POLYPEPTIDE with said drug candidate to be screened in the presence of components capable of providing a detectable signal in response to DNase-X activity under conditions to allow continued DNase-X activity and b) detecting presence or absence of a signal or increase of the signal generated from DNase-X activity wherein the presence or increase of the signal is indicative of a putative drug.

Group 6, claim(s) 38 and 43, drawn to a probe and a kit for detecting cancer, the probe being capable of specifically binding to or reacting with DNase-X POLYPEPTIDE and being capable of indicating a level of DNase-X POLYPEPTIDE in a biological test sample.

Group 7, claim(s) 38 and 43, drawn to a probe and a kit for detecting cancer, the probe being capable of specifically binding to or reacting with DNase-X NUCLEIC ACID and being capable of indicating a level of DNase-X NUCLEIC ACID in a biological test sample.

Group 8, claim(s) 40-42 drawn to a kit/ pharmaceutical composition for the treatment of carcinomas and their precursor lesions, comprising a drug candidate identified in claim 39.

The inventions listed as Groups 1-8 do not relate to a single general inventive concept under PCT Rule 13.1 because unity of invention between different categories of inventions will

only be found to exist if specific combinations of inventions are present. Those combinations include:

A) A product and a special process of manufacture of said product.

B) A product and a process of use of said product.

C) A product, a special process of manufacture of said product, and a process of use of said product.

D) A process and an apparatus specially designed to carry out said process.

E) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The inventions of groups 1-8 are drawn to multiple products as well as multiple methods of using those products. Allowed combinations do not include multiple products, and multiple methods of using said products, as claimed in the instant application. Hence, only one product and one process of use of said product relate to a single general inventive concept. Since multiple products and multiple methods with different special technical features are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d).

Accordingly, Groups 1-8 are not so linked as to form a single general inventive concept and the finding of lack of unity is proper.

Group 1 is drawn to a method of detecting DNase X polypeptide for the detection of carcinomas.

Group 6 is drawn to a product for use in Group 1.

Groups 2-5, 7, and 8 are drawn different products and methods of using those products.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

3. During a telephone conversation with Blair Lanier on June 1, 2006 a provisional election was made without traverse to prosecute the invention of Group 6, claims 38 and 43. Affirmation of this election must be made by applicant in replying to this Office action.

4. In view of the prior art, Groups 6 and 7 will be rejoined.

5. Claims 27-37 and 39-42 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Claims 38 and 43 are currently under consideration.

Specification

5. The amendment filed 5/18/2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: A peptidomimetic is a synthetic peptide having nonnatural amino acids that is capable of mimicking a biological property of a natural parent peptide (Denicourt et al., Science. 305 (2004) 1411-13).

Applicant is required to cancel the new matter in the reply to this Office Action.

6. The specification is further objected to on page 86, paragraph 260, of the specification submitted 6/16/2005 for improper disclosure of amino acid sequences without a respective sequence identifier, i.e. a SEQ ID NOs: Hence, the disclosure fails to comply with the requirements of 37 CFR 1.821 through 1.825. In the absence of a sequence identifier for each sequence, Applicant must provide a computer readable form (CRF) copy of the sequence listing, an initial or substitute paper copy of the sequence listing, as well as any amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e-f) or 1.825(b) or 1.825(d). *Failure to supply the appropriate sequences identification numbers in response to this action will be considered non-responsive.*

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 43 is indefinite because it cannot be determined what a positive control associated with an absence of carcinomas is. Is it a sample from sources that are not carcinomas or precursor lesions? Is it a sample that indicates the absence of carcinoma or precursor lesions by some other marker? Is it a sample from cancer patients that have had their carcinomas or precursor lesions treated and cured? Thus the metes and bounds of the claims cannot be determined.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation of *a DNase-X polypeptide or nucleotide positive control sample associated with an absence of carcinomas or their precursor lesions* has no clear support in the specification and the claims as originally filed. Examiner's review of the specification did not reveal support for

the newly added limitation. Applicant is invited to submit evidence pointing to page and line number in the specification wherein support for the newly added limitation can be found. The subject matter claimed in claims 43 broadens the scope of the invention as originally disclosed in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 38 is rejected under 35 U.S.C. 102(b) as being anticipated by Los et al. (Biochemistry 31 May 2000, 39:7365-7373).

The claim is drawn to a probe for detecting cancer, the probe being capable of specifically binding to or reacting with DNase-X polypeptide or nucleic acid and being capable of indicating a level of DNase-X polypeptide or nucleic acid in a biological test sample.

It is noted that the preamble recitation of "a probe for detecting cancer" is merely suggestive of an intended use and is not given weight for purposes of comparing the claims with the prior art. The claims read on the active ingredient *per se*, the probe being capable of specifically binding to or reacting with DNase-X polypeptide or nucleic acid.

Los et al. teach a probe labeled DNase X cDNA for detection of DNase-X transcripts in a Northern blot, see p. 7366, right col. and Fig. 6. Los et al. teach rabbit anti-DNase X antibodies used in immunoblotting, see p. 7366, left col. and Fig. 6.

Although the reference does not specifically state that the DNase X cDNA and antibodies are probes for detecting cancer, the claimed product appears to be the same as the prior art product, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Los et al. (Biochemistry 31 May 2000, 39:7365-7373) to claim 38 above, and further in view of Stratagene Catalog 1988, p. 39.

Claim 43 is drawn to a kit comprising a) a probe according to claim 38; and b) a DNase-X polypeptide or nucleotide positive control sample associated with an absence of carcinomas or their precursor lesions.

Given the indefinite nature of the claims it is assumed for examination purposes that positive control samples are samples from non-carcinoma or precursor lesion sources.

It is noted that the preamble recitation of "a probe for detecting cancer" in claim 38 is merely suggestive of an intended use and is not given weight for purposes of comparing the claims with the prior art. The claims read on the active ingredient *per se*, the probe being capable of specifically binding to or reacting with DNase-X polypeptide or nucleic acid.

Los et al. teaches as set forth above and teaches a multiple normal tissue Northern blot that contains a DNase X nucleotide, mRNA, purchased from Clontech which is clearly a sample associated with an absence of carcinomas or their precursor lesions, see p. 7366, right col., p. 7371, left col., and Fig. 6. Los et al. teach SKW6.4, B-lymphoblast cell extracts that contain DNaseX polypeptide and bacterial extracts overexpressing recombinant DNase X polypeptide which are positive control DNase X polypeptide samples associated with an absence of carcinomas, see Fig. 1 and Fig. 6.

Los et al. do not teach a kit comprising a DNase X probe or positive control sample for a DNase X polypeptide or nucleic acid.

The Stratagene Catalog teaches reasons and motivation to combine reagents into a kit format (see page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the probe being capable of specifically binding to or reacting with DNase-X polypeptide or nucleic acid and being capable of indicating a level of DNase-X polypeptide or nucleic acid in a biological test sample and the DNase X polypeptide and cDNA positive control samples into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control" (page 39, column 1).

Although the reference does not specifically state that the DNase X cDNA and antibodies are probes for detecting cancer, the claimed product appears to be the same as the prior art product, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed

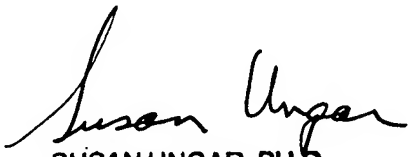
product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA)

11. No claims allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



SUSAN UNGAR, PH.D
PRIMARY EXAMINER

Peter J. Reddig
Examiner
Art Unit 1642

PJR

Notice to Comply	Application No. 10/539,233	Applicant(s) Coy	
	Examiner Peter Reddig	Art Unit 1642	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: The disclosure is lacking numerous sequence identifiers and sequence ID numbers, see the section titled "Sequence Listing" in the accompanying First Office Action on the Merits.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
For CRF Submission Help, call (703) 308-4212 or 308-2923
PatentIn Software Program Support
Technical Assistance.....703-287-0200
To Purchase PatentIn Software.....703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, DC 20231
www.uspto.gov

APPLICATION NO. /CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10/359,233	06/16/2005	Johannes Coy	4007.009

EXAMINER	
Peter Reddig, Ph.D.	
ART UNIT	**PAPER**
1642	

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

This application discloses amino acid sequences without a respective sequence identifier, i.e. a SEQ ID NO on page 86, paragraph 260, of the specification submitted 6/16/2005. Hence, the disclosure fails to comply with the requirements of 37 CFR 1.821 through 1.825. In the absence of a sequence identifier for each sequence, Applicant must provide a computer readable form (CRF) copy of the sequence listing, an initial or substitute paper copy of the sequence listing, as well as any amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by matter, as required by 37 CFR 1.821(e-f) or 1.825(b) or 1.825(d).

If a complete reply has not been submitted by the time period set in the accompanying Office action has expired, this application will become abandoned under 37 CFR 1.821(g).

Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned Applicant is requested to return a copy of the

attached Notice to Comply with the reply.

Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:

1. Electronically submitted through EFS-Bio (http://ww.uspto.gov/ebc/efs/downloads/documents.htm>, EFS Submission User Manual-ePAVE)

2. Mailed to

Mail Stop Sequence

Commissioner for Patents

P.O. Box 22313-1450

Alexandria, VA 22313-1450

3.Hand Carry, Federal Express, United Parcel Service or other delivery service to:

U. S. Patent and Trademark Office

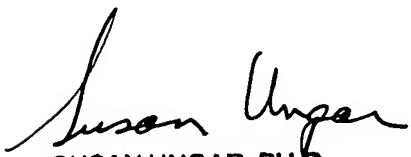
Mail Stop Sequence

Customer Window

Randolph Building

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Reddig whose telephone number is 571-272-9031. The examiner can normally be reached on M-F 8:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached at 571-272-0898.



SUSAN UNGAR, PH.D
PRIMARY EXAMINER

Peter Reddig, Ph.D.
Art Unit 1642

Sequence Count Sheet	Application/Control No.	Applicant(s)	
	10/539,233	Coy	
	Examiner	Art Unit	
	Peter Reddig	1642	

DATE OF COUNT

Mark only one space below

☐ **(CRFN)** (CRF is unreadable; use CRF Diskette Problem Report)

☐ **(CRFD)** (CRF does not comply; use Notice to Comply)

☐ **(CRFR)** (CRF required but none submitted; use Notice to Comply)

☒ **(bona fide)** (second or subsequent letter to applicant reporting bona fide attempt to comply; use Notice to Comply and send copy of RSL)

☐ **(non bona fide)** (second or subsequent letter to applicant reporting non-bona fide attempt to comply; use Notice to Comply and send copy of RSL)